

REMARKS

This Response is being filed with a Request for Continued Examination (RCE) so that prosecution of the subject application may be continued. The undersigned attorney, William A. Blake, discussed non-substantive procedural matters with Examiner Schaetzle during a telephone conversation a few months ago. During the call, Mr. Blake informed Examiner Schaetzle of Applicants' intent to file a Response with an RCE and asked whether a telephone interview could be conducted prior to the next action on the case. Examiner Schaetzle agreed to this proposal. Accordingly, the undersigned attorney would like to thank Examiner Schaetzle in advance for agreeing to the interview and will call Examiner Schaetzle once this Response is filed to schedule the interview.

In the latest Office Action of June 13, 2008, which the Examiner has made final, the Examiner has maintained the rejections of the claims as being obvious under 35 U.S.C. 103 and the arguments in support thereof. In responding to the arguments presented by the Applicants in the last Amendment, the Examiner has made a number of additional assertions as set forth below. Applicants have carefully considered the Examiner's position and respectfully submit that the position is clearly in error for the reasons given below.

For the record, claims 11, 14, 16-21 and 23-26 stand rejected under 35 U.S.C. 103(a) as being unpatentable over Andrews et al. (Pat. No. 6,186,977, hereinafter referred to as "Andrews"). The remaining pending claims, 22 and 27, stand rejected under 35 U.S.C. 103 as being unpatentable over Andrews in view of Dudley (Pat. No. 3,905,363) or Sundblom et al. (Pat. No. 3,820,566).

Also for the record, the claimed invention is directed to an emergency medical system of a size and weight that can be easily carried with one hand and includes a source of medical

oxygen and a defibrillator for patient treatment and at least one measurement system for measuring a blood or gas parameter of the patient. A number of other adjuncts can be included as set forth in the dependent claims. The purpose of the invention is to provide a convenient easily transported unit for emergency medical and lay first-aid responders, which provides the multiple functions of a source of emergency medical oxygen, a defibrillator and device(s) for patient diagnosis and/or monitoring. The unit can be easily carried with a single hand by emergency responders to the victim or patient at an accident scene, for example, up and down stairs, maneuvering around tight corners, easily in and out of transport vehicles, up and down hills in various terrains in the field, and avoids the need to collect and carry multiple separate pieces of equipment which is inconvenient and would likely necessitate use of both hands.

As will be established below, the rejection of claim 11 over Andrews is clearly in error based on the following reasons. First, Applicants respectfully submit that the US Supreme Court ruling in *KSR International Co. v. Teleflex Inc.*, 127 S. Ct. 172, 782 USPQ2d 1385, 1396 (2007) (hereinafter “KSR”) does not change the fact that Andrews does not render claim 11 obvious under 35 U.S.C. 103. This is because KSR did not alter the fundamental well established requirement that a *prima facie* case of obviousness must be established by the Examiner that does not rely on the impermissible use of hindsight through reference to Applicants’ own disclosure. Instead, KSR dealt with a situation where the teachings of two references were combined and admittedly established a *prima facie* case of obviousness under 35 U.S.C. 103. The issue was whether the Court of Appeals for the Federal Circuit (CAFC) had correctly applied the well known TSM (Teaching, Suggestion, Motivation) test in finding that the teachings of the two references were not properly combinable. The Supreme Court overruled the CAFC and held that the CAFC had applied the TSM test too rigidly. In doing so, the Supreme

Court did not eliminate the TSM test, noting that it provides helpful insights into whether a combination of references renders a claim obvious under 35 U.S.C. 103, but noted other issues that should be considered in determining obviousness. Still the Court reiterated that hindsight is to be avoided.

The present case is clearly not concerned with the issue of whether a combination of references is proper since only a single reference is being relied upon in the rejection. However, it is apparent that the Examiner has applied one of the new standards set forth by the Supreme Court in KSR referred to as “obvious to try” in an attempt to establish that it would be obvious to modify the apparatus disclosed in Andrews and arrive at the invention recited in claim 11. As will be established, Applicants respectfully submit that Andrews clearly does not establish a *prima facie* case of obviousness as to any of the claims. In particular, Andrews does not disclose or suggest the key feature of the invention, which is the provision of an emergency oxygen and defibrillator resuscitation unit (with one or more adjuncts) which are contained within a unitary housing that is easily carried by a single hand. More importantly, modifying the apparatus disclosed in Andrews in such a way that it would anticipate claim 11 would, by the very nature of the Andrews apparatus, require such extensive modifications that the resulting device would no longer be suitable for the purpose for which the Andrews device is intended. For this reason, the suggested modifications cannot support a *prima facie* case of obviousness based on the provisions of MPEP§2143.01(V). Not surprisingly, the “obvious to try” test set forth in MPEP§2143(E) is also not satisfied by the teachings of Andrews for the same reason and also because there would be no need in 1998 (or even now for that matter) to try to put all of Andrews equipment in a unitary housing that is easily carried by a single hand. The foregoing reasons are discussed in detail below.

The pertinent portions of the MPEP as amended in response to KSR are provided below, starting with the following excerpt from MPEP§2142 as it currently reads regarding establishment of a *prima facie* case of obviousness under 35 U.S.C. 103:

“To reach a proper determination under 35 U.S.C. 103 the examiner must step backward in time and into the shoes worn by the hypothetical "person of ordinary skill in the art" when the invention was unknown and just before it was made. In view of all factual information, the examiner must then make a determination whether the claimed invention "as a whole" would have been obvious at that time to that person. Knowledge of applicant's disclosure must be put aside in reaching this determination, yet kept in mind in order to determine the "differences," conduct the search and evaluate the "subject matter as a whole" of the invention. The tendency to resort to "hindsight" based upon applicant's disclosure is often difficult to avoid due to the very nature of the examination process. However, impermissible hindsight must be avoided and the legal conclusion must be reached on the basis of the facts gleaned from the prior art.

ESTABLISHING A *PRIMA FACIE* CASE OF OBVIOUSNESS

The key to supporting any rejection under 35 U.S.C. 103 is the clear articulation of the reason(s) why the claimed invention would have been obvious. The Supreme Court in *KSR International Co. v. Teleflex Inc.*, 550 U.S. ___, ___, 82 USPQ2d 1385, 1396 (2007) noted that the analysis supporting a rejection under 35 U.S.C. 103 should be made explicit. The Federal Circuit has stated that "rejections on obviousness cannot be sustained with mere conclusory statements; instead, there must be some articulated reasoning with some rational underpinning to support the legal conclusion of obviousness." *In re Kahn*, 441 F.3d 977, 988, 78 USPQ2d 1329, 1336 (Fed. Cir. 2006). See also *KSR*, 550 U.S. ___, ___, 82 USPQ2d at 1396 (quoting Federal Circuit statement with approval)."

The "obvious to try" test that was set forth in the KSR decision is discussed in MPEP§2143(E), which reads as follows:

“E. "Obvious To Try" - Choosing From a Finite Number of Identified, Predictable Solutions, With a Reasonable Expectation of Success

To reject a claim based on this rationale, Office personnel must resolve the *Graham* factual inquiries. Then, Office personnel must articulate the following:

(1) a finding that at the time of the invention, there had been a recognized problem or need in the art, which may include a design need or market pressure to solve a problem;

(2) a finding that there had been a finite number of identified, predictable potential solutions to the recognized need or problem;

(3) a finding that one of ordinary skill in the art could have pursued the known potential solutions with a reasonable expectation of success; and

(4) whatever additional findings based on the *Graham* factual inquiries may be necessary, in view of the facts of the case under consideration, to explain a conclusion of obviousness.

The rationale to support a conclusion that the claim would have been obvious is that "a person of ordinary skill has good reason to pursue the known options within his or her technical grasp. If this leads to the anticipated success, it is likely that product [was] not of innovation but of ordinary skill and common sense. In that instance the fact that a combination was obvious to try might show that it was obvious under § 103." *KSR*, 550 U.S. at ___, 82 USPQ2d at 1397. If any of these findings cannot be made, then this rationale cannot be used to support a conclusion that the claim would have been obvious to one of ordinary skill in the art." (emphasis added)

Finally, MPEP§2143.01(V), which is also clearly relevant to the present case, states that the proposed modification cannot render the prior art unsatisfactory for its intended purpose.

This section reads as follows:

"If the proposed modification would render the prior art invention being modified unsatisfactory for its intended purpose, then there is no suggestion or motivation to make the proposed modification. *In re Gordon*, 733 F.2d 900, 221 USPQ 1125 (Fed. Cir. 1984)"

In the Office Action, although *KSR* is not specifically mentioned, it is apparent that the Examiner clearly relied upon the "obvious to try" test in his attempt to establish the obviousness of the claimed invention over Andrews by asserting the following:

"Given the general desire and recognized need in emergency medical situations to provide lightweight, portable equipment, and given the various court cases and

teachings of Andrews et al. elaborated above, those of ordinary skill in the emergency medical treatment art would have considered it obvious to make the system of a size and weight to allow single hand/hand-held portability. It is the type of emergency and patient most likely to be encountered that would dictate the equipment necessary to be contained within the casing and thus the relative size and weight of the overall system. All of the systems recited by the applicants are old and well-known in the prior art. With a reasonable expectation of success, one skilled in the art could have combined the elements as claimed with no change in their respective functions, and the combination would have yielded nothing more than predictable results. For all of the above reasons, one of ordinary skill in the art would have at least found it obvious to try making the system of a size and weight which can easily be carried by a single hand or hand-held.” (Office Action, pp. 3-4)

Applicants respectfully submit that the foregoing quote is strong evidence in and of itself that the Examiner used impermissible hindsight through reference to Applicants’ own disclosure to reach the conclusion that claim 11 is obvious over Andrews. More particularly, it is apparent that the Examiner is reading language from Applicants’ own application into Andrews. The Examiner concludes that Andrews relates to a device for use in emergency medical treatment, but this is not an accurate statement and nowhere in Andrews is the word “emergency” used even once. Instead, Andrews is directed to an anesthesia administering apparatus that can be used for ambulatory outpatient type surgeries and associated applications as evidenced for example by the following passage from col. 6, lines 59-64 of Andrews:

“The present invention may be used in many applications, particularly for ambulatory surgery, such as, for example, for cosmetic surgery, dermatology, dentistry and podiatry. Associated applications may likely include critical care services in transport, military applications, MRI, and commercial airlines.”

It is apparent from the above passage that the purpose of the Andrews device is to provide an anesthesia apparatus that can be used to anesthetize patients for surgeries conducted

in other than traditional operating room environments. For example, the definition of “ambulatory surgery” is surgery or procedures performed in an outpatient setting and not so intensive as to require a hospital stay (ie: the patient ambulates to and from an ambulatory surgery center). The Andrews device could thus arguably be placed on board a military and transport aircraft, for example, so that various surgeries and associated critical care services could be performed on various patients at various locations while being transported on board. There is clearly no disclosure or suggestion in Andrews, however, that the disclosed device be used at the actual scene of an emergency, remote in the field for example, where no surgeon is likely to be present anyway so that Andrews’ anesthesia apparatus would be of no use. Thus, there simply would be no reason to try to make the Andrews anesthesia apparatus fit in a housing that is readily carried by a single hand, for there would be no advantage in doing so and too many of the desired components of the apparatus would have to be left out, especially considering the relative size of such components at the relevant time frame of 1998.

The Examiner has obviously confused Andrew’s ambulatory surgery and associated critical care services with Applicants’ emergency treatment by lay first responders and emergency medical technicians (EMTs) of victims at the scene of an accident or other emergency site, for example. Lay responders and EMTs are not surgeons and have no need for anesthesia administering equipment at the immediate scene of an accident or other medical emergency. What they do have a need for is an emergency oxygen supplying equipment and defibrillator for resuscitation with a diagnosis measuring device that can help save a person’s life at the scene of the emergency. It is the lay responders and EMTs that thus have a need for emergency equipment that can be easily carried by a single hand.

The Examiner's following comments on page 10 of the Office Action in the Response to Arguments section provide additional support for the fact that the Examiner has misconstrued the Andrews apparatus to be intended for applications at the initial emergency scene:

"The applicant further argues that the applications mentioned in col. 6, lines 59-67 to support the contention that one of ordinary skill would have been motivated towards compact design, are all relatively stationary locations and not even near the size and weight that can be carried by a single hand. The examiner disagrees. Compact design is crucial to military or commercial airlines applications where excess weight and size can have very detrimental consequences. It would be in the very least obvious for one of ordinary skill in the art to design an airline or military emergency medical system with the most compact components available in an effort to save space and weight - decided and recognized advantages in both aviation and/or military applications." (emphasis added)

As set forth previously, MPEP§2143.01(V) states that the proposed modification cannot render the prior art unsatisfactory for its intended purpose. Applicants respectfully submit that the extensive modifications that are necessary to the Andrews apparatus in order to establish a *prima facie* case of obviousness as to claim 11 using this single reference clearly not only rely on the impermissible use of hindsight, but also would render the device in Andrews unsatisfactory for its intended purpose.

In effect, the Examiner is asserting that the key features of the subject claimed invention, disposing the recited components in a unitary housing that is easily carried with a single hand, would be obvious under the guise that making something smaller or portable is not in and of itself patentable. However, this ignores the fact that the claims specifically recite a unitary housing that is easily carried by a single hand for a reason: so that emergency medical technicians in the field at the scene of an emergency, for example, can keep one hand free as they make their way to an individual in need of emergency oxygen and defibrillator resuscitation.

Thus, by no means is the claimed invention just a smaller version of the Andrews device, which could, for example, be more easily pushed on its casters or could more easily fit down the aisle of an aircraft. There simply is no disclosure or suggestion in Andrews to modify the device in such a manner that it can be easily carried by a single hand. Only through the impermissible use of hindsight, would one of skill in the art decide to modify Andrews's device and purpose to make a portable emergency oxygen and defibrillator resuscitation unit as recited in claim 11 and the dependent claims.

To satisfy the requirement of MPEP§2143(V), at a bare minimum, any obvious variation of the Andrews device must include the anesthesia administering components and necessary support components, for without these components, the purpose of Andrews is unquestionably defeated. That being said, in order to render claim 11 obvious, the emergency oxygen source, defibrillator and measurement system would also have to be left in the housing and then the housing would have had to be made easily carried by a single hand. The emergency resuscitation components clearly are usable by lay responders and EMTs in the field. However, lay responders and EMTs are not surgeons and they will not be administering anesthesia to a victim at an accident scene, for example, so that some type of surgery can be performed on the side of the road.

It is quite apparent from a reading of Andrews, that the disclosed apparatus for administering anesthesia is by no means intended to be disposed in a housing that is readily carried by a single hand. On the contrary, the device is clearly intended to include numerous components that no one would ever consider trying to fit into a unitary housing that can be carried by one hand. In fact, Andrews teaches away for such a proposition by noting the desire to be as compact and portable as possible, but recognizes that casters or wheels 18 are necessary

for this purpose, obviously to accommodate all of the equipment that is necessary in a surgical environment where a patient is fully anesthetized.

It is correct that Andrews discloses that the device can be modified for various uses including military applications, etc. Nowhere, however, is any suggestion made that the device's purpose, to provide an anesthesia administering apparatus for use in an ambulatory surgical setting, be compromised. Not surprisingly then, the device preferably includes not only infusion pumps, IV bags and patient monitoring equipment, but also a storage cabinet for surgery related purposes. It is thus clear that the Andrews device is not an emergency resuscitation device; it is an anesthesia delivery apparatus which optionally includes a resuscitation unit as disclosed later in the description. On the other hand, the storage cabinet 11 is one of the first components discussed in Andrews. Being an anesthesia administering device, it is also clear that the device is intended to be used in surgical settings where anesthesia is required. This is obviously why the preferred embodiment of Andrews includes the storage cabinet 11 with all types of surgical equipment including storage bins, trash receptacles, etc that would be typically employed in a surgical setting. In fact, the preferred embodiment even includes a flat working surface for use during an anesthesia administering procedure. It is therefore not surprising that Andrews does not disclose or suggest that the apparatus be contained in a unitary housing that is easily carried by a single hand; first, because to do so would require leaving out too many of the necessary components and second, because there would be no reason to try to make the device that small to begin with.

Applicants stress the foregoing aspects of the Andrews apparatus because MPEP§2143.01(V) clearly infers that a *prima facie* case of obviousness is not established if the

modifications of the device disclosed in the reference defeat the purpose of the device. The

Examiner asserts in response to Applicants' arguments on this point the following:

"it is not clear why the elimination of various components of the Andrews et al. invention would "completely defeat the whole purpose" of the invention when Andrews et al. explicitly disclose that many modifications and other embodiments of the invention may be employed. Furthermore, use of the term "comprising" in the claim preambles does not limit the present invention to just the elements recited." (Office Action, page 9)

The foregoing argument is flawed for a number of reasons. The only way to have put Andrews's anesthesia apparatus in a hand held suitcase, for example, would have been to leave out much of the equipment that the preferred embodiment employs. Applicants admit that claim 11 uses the term comprising and thus does not exclude other components in addition to those recited in the claim. However, this fact misses the point. The only way to avoid defeating the purpose of Andrews's device in any modification thereof would require not only leaving the anesthesia components intact, but also leaving the cabinet 11 and the numerous patient monitors intact as well.

Regarding the "obvious to try" test, the foregoing arguments also clearly establish that at least two of the required findings of the test are not satisfied in this case and thus cannot be applied to modify the Andrews device in the manner asserted by the Examiner. In particular, findings (1) and (3) of the test clearly are not present in this case. Finding (1) requires that at the time of the invention, there had been a recognized problem or need in the art, which may include a design need or market pressure to solve a problem. As already noted, the desired portability of the Andrews device by no means is indicative that there was a need in 1998 to try to fit Andrew's anesthesia administering apparatus in a housing that is readily carried by a single

hand. Clearly, there would be no need to make the apparatus that compact. Further, finding (3) of the test is not satisfied either. Finding (3) requires that one of ordinary skill in the art could have pursued the known potential solutions with a reasonable expectation of success. One of ordinary skill in the art having the teachings of only Andrews before them, would never think that it would be possible to fit the Andrews apparatus into a unitary housing that could be readily carried by a single hand for the reasons elaborated previously. Thus, there would be no reasonable expectation of success in doing so. As a result, there is no support for the modification to the Andrews device asserted by the Examiner and thus, Andrews does not establish a *prima facie* case of obviousness as to claim 11 or any of the dependent claims.

One further point should be noted. As mentioned briefly earlier, the subject reissue application has an effective filing date that goes back 10 years to September 11, 1998, which is the filing date of the original application, USAN 09/151,300, that subsequently issued as US Patent 6,327,497. As such, because MPEP§2142 states that "...the examiner must step backward in time..." it is illuminating that in the Office Action of March 21, 2001 during prosecution of the '300 application, at a time much closer to the time of the subject invention (2½ years then vs 10 years present), Andrews was specifically noted as not rendering the broad claims therein unpatentable. The specific statement, made by Examiner Schaetzle, who is the Examiner of record in the subject application, reads as follows:

"...There is no teaching in the prior art of record for combining a defibrillator with a breathable oxygen delivery system in a unitary, hand-held, portable housing. Andrews et al. shows the two systems employed in a single portable unit, but the device is not considered to be hand-held in view of the applicants comments (the examiner will consider the term *hand-held* to be to be limited to devices of a size and weight which can easily be carried by a single hand)...". (Office Action of March 21, 2001, page 4)

Applicants respectfully submit that the foregoing analysis is still correct and can also apply to the claims currently under examination, which are similar to the claims allowed in the parent '497 patent and in Reissue Patent No. 38,533. Two notable things have occurred since Examiner Schaetzle made the above statement. First, more than 7 years have passed and second, the KSR case has been decided by the Supreme Court. As to the first, the passage of that much time can only serve to make it even more difficult to step back in time as required by MPEP§2142, which was certainly easier more than 7 years earlier. As for KSR, while this case has admittedly changed the law of obviousness, the changes do not impact the present case where a *prima facie* case of obviousness is not established by the single cited reference. Thus, the Examiner's conclusion that Andrews did not render similar claims in the parent nor the reissue patent obvious is still valid and appropriate in the present case.

In conclusion, the suggestion that one of ordinary skill in the art, having only the teachings of Andrews before them, would lead them to the conclusion that the device could be modified to be readily carried by a single hand is completely untenable because the preferred embodiment in Andrews simply employs too much equipment for it to be housed in a unitary housing that is easily carried by a single hand. Thus, any attempt to do so would defeat the purpose of the Andrews device (anesthesia administering device for ambulatory surgery applications or the like). Furthermore, unlike for use by lay responders and EMTs in the field, ambulatory surgery and the other applications recited in Andrews for the Andrews apparatus create no need for trying to make the apparatus so small in the first place. Clearly, the recent decision in KSR has by no means eliminated the prohibition against the impermissible use of hindsight, nor has that case changed the rule in MPEP§2143.01(V) that a modification cannot defeat the purpose of the invention. Not surprisingly then, the "obvious to try" test set forth in

KSR clearly does not apply to the present case either. For these reasons, the rejection of claim 11 and all of the dependent claims over Andrews et al and the other references of record is clearly in error and should be removed. Accordingly, favorable reconsideration of the application is respectfully requested.

Respectfully submitted,

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